Bed Safety Consulting, Inc.

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Dear Sir:

Subject: The Draft Guidance for Industry and Food and Drug Administration Staff, from the document: **Hospital Bed System Dimensional Guidance to Reduce Entrapment** issued August 30, 2004.

In response to the FDA's request for comments and suggestions relating to the Guidance identified above, I have prepared the following document for your consideration. This document consists of five pages of text, one attachment of two pages, and two separate figures. As per your instructions, all of these pages have been identified as belonging to docket number 2004-0343.

If I can be of any further assistance, please feel free to contact me at 315-337-0308.

Your Truly,

William Schatz
President

cc: Joan Ferlo Todd

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Comments and suggestions regarding the draft guidance for Industry and Food and Drug Administration Staff, from the document: **Hospital Bed System Dimensional Guidance to Reduce Entrapment**.

Background:

In addition to being the President of Bed Safety Consulting, Inc., I am also a specialist in bed safety for a public sector agency that oversees services to a large number of developmentally disabled individuals. Responding to a number of bed rail entrapment incidents, the public agency with whom I am employed began a statewide program in 1995 to investigate and take whatever corrective actions were needed to eliminate deaths and injuries associated with bed rail entrapment My comments and suggestions are derived from the ten years of experience that I have gained in developing, implementing, and enforcing bed safety standards which are now being applied to over 35, 000 beds.

When an institutional center for developmentally disabled persons closes, the last item to be moved is the resident's bed system. In the late 1980's, developmental center closure was occurring in this State on a grand scale and under very stringent deadlines. These two factors combined with movers who had no training in the proper assembly of bed systems, many residents who were at extreme risk of entrapment, a greatly reduced level of night time supervision, and the staff's lack of awareness of the potential for entrapment, inadvertently brought together those factors that are the causal links to bed rail entrapment deaths.

As a member of the user based, statewide committee, that was charged with discovering and resolving the causes of bed rail entrapment, our response to this assignment was to expand on formal incident reports with both direct observations of the bed systems involved and interviewing the staff who actually discovered either an entrapment death or a near miss to build an information base. This information base was initially used to develop educational materials and then used to develop the attached Bed Safety Checklist, Attachment #1. With very minor changes that were made in 2002, this Checklist has been enforced across this State since March 10, 1999. I am pleased to report, that after 60 million patient days, there has not been one, single bed rail entrapment death in those 35,000 beds which are being inspected annually for compliance with the standards contained within the Bed Safety Checklist.

There are several reasons for extending the lessons learned from this State's Bed Safety Program that was designed for a mentally retarded population to a national bed safety program for bed systems used by the general population. First, the mentally retarded, developmentally disabled population is inherently at a much higher risk of entrapment than the general population. Second, it takes a lot of deficient beds to develop sufficient insight as to how small the allowable gaps must to be in order to prevent entrapment. Third, there are no special hospitals for the retarded, when they get sick or need surgery they go to the very hospitals that this guidance is directed. Therefore, like the canary in the mineshaft, it is my contention that bed systems that are safe for the developmentally disabled population will be safe for all users.

General Comment relating to the least burdensome approach to reducing the number of hospital bed entrapments, page 2 of the draft. You will note from my background comments, I have been involved with attaining a much more difficult goal than reducing the number of bed rail entrapment deaths, i.e. eliminating them. In this State, an information/ educational strategy was the first step that was taken to eliminate bed rail entrapment deaths. The efficacy of this strategy proved to be inadequate to achieve our goal. It was tragically demonstrated that despite the best of intentions, voluntary compliance does not have sufficient strength to motivate decision makers to inspect, upgrade, and maintain all their beds in compliance with safety standards. It was not until compliance with the Bed Safety Checklist was included as a component of the annual certification process that bed rail entrapment deaths were stopped.

While it is possible that this least burdensome approach might occasionally reduce the annual number of bed rail entrapment deaths, this is a flawed goal. Bed rail entrapment deaths are totally preventable and they take place in an environment that is ironically focused on the health and well being of the victim. Given these facts, there is no level or number of bed rail entrapment deaths that can ever be written off as acceptable. This least burdensome approach coupled with the large dimensional gaps that are proposed in this Guidance will guarantee that these abhorrent deaths will continue for years to come.

Comment #1 relating to product exclusions, page 7 of the draft. There is no inherent incompatibility between either framed flotation therapy products or powered air mattress replacements and bed safety standards. As such. the FDA should not exclude these products from the application of dimensional limits.

Of greater concern is the fact that the width of mattresses, twin beds with bed rails and attachment hardware have been omitted from this draft Guidance. This State's Checklist, Attachment #1, clearly recognizes the contribution that a mattress of the proper width can make in preventing bed rail entrapments. Checkpoints # 2, #3 and # 18 focus on the width and performance of the mattress. See Figure #1.

Similarly, many hard lessons have been learned about the danger of entrapment that is created when bed rails are attached to twin beds. Checkpoints #1 through #14 are used with both hospital and twin beds, while Checkpoints #15, #16, and #17 are specific Checkpoints for twin beds. Needless to say, the emphasis placed on these two products is derived from our accident history and I am strongly suggesting that the FDA expands the scope of this guidance to include both mattress width and twin beds with side rails.

Also of significance is the fact that this Guidance ignores the design of the hardware used for securing the bed rail to the bed. The most significant gaps, produced between the bed rails and the bed, are by-products of the hardware that is used to attach the bed rails. For example, Zone 4 is a total artifact produced by the design and location of the attachment mechanism in a split side rail system. In my opinion a large opportunity to improve the safety of all bed systems has been overlooked. I urge the FDA to include this hardware because crossbars are single greatest contributor to bed rail entrapment.

Comment #2 relating to a more stringent dimensional limit at Zone 2, page 15 of the draft. From the Checklist, point number #10 addresses this Zone. You will note that compliance with #10, when the bed is flat, is achieved by having the bottom bar of the side rail overlapping the side of the mattress. Thus, there is no acceptable gap between the bottom of the side rails and the mattress. In a flat bed, our experience has shown that using an overlapping starting position prevents the creation of under bar entrapment gaps due to variations in the weights of the bed users and variations in the indices of load deflection presented by different mattresses. Also, compliance with this overlap standard is easily confirmed on a pass/fail basis by observation. No special tool or measurement device is needed. It has been our experience that there is a great benefit realized, when all the persons involved with purchasing, assembling, making, adjusting, maintaining and inspecting a bed system understand and can readily verify this safety component of a bed.

See **Comment # 7** for my response for a more stringent dimensional limit to Zone 2 once the bed is articulated.

Comment #3 relating to a more stringent dimensional limit at Zone 3, page 16 of the draft. It is disturbing to me that a lateral gap as large as 4 3/4" inches was ever even suggested for such a high-risk location. The statewide investigation and ongoing monitoring into near misses and deaths repeatedly confirmed that in order to be safe, this gap must be kept as minimal as physically possible. Checkpoint #2 from the Checklist, Attachment #1, describes a procedure for measuring an acceptable gap in Zone 3, it states:

"With the mattress pushed against one rail, the space between the mattress and the other side rail is minimal if any. ["Minimal space" is when you feel resistance on both sides of your **OPEN** hand when you place it between the mattress and the side rail]"

The width of an open hand is approximately ¾" of and inch, which is over 6 times smaller than the 4 ¾" inches contained in the draft guidance. I cannot overstate how important it is to minimize this gap.

Regrettably, only split side rails have been used to exemplify entrapment possibilities. Split side rails fail to demonstrate the full entrapment potential within Zone 3 that is present when full-length side rails are used, see Figure 1. Accordingly, the belief that the head blocks the entry of the neck into this gap is not true. With full length side rails, the legs slide between the side rail and the mattress and the weight of the legs pulls the trunk through the Zone 3 gap until either the chest or the head becomes entrapped.

Once again, compliance with this open hand standard is easily confirmed on a pass/fail basis by application. No special tool or measurement device is needed. Surprisingly, there have been very few hair splitting arguments that were based on the differences in the actual width of the site staff's and the inspector's hands. This low-tech approach to measuring the acceptable limits of the lateral gap empowers the staff on site to discover and remedy an unsafe gap without waiting for the inspector's annual visit.

Comment #4 relating to a dimensional limit for Zone 5, page 20 of the draft. This State's Checklist, Checkpoint #21, uses similar limits of between 2 1/3" and 10" inches as the prohibited gap for the space between split side rails.

Comment #5 relating to a dimensional limit for Zone 6, page 21 of the draft. From the experience gained in this State, the contribution of Zone 6 to bed rail entrapment is under appreciated. Following manufacture's instructions, Checkpoint #8 was originally written in 1999 as:
"Cross bars are located appropriately for the consumer, i.e. top bar approximately under the consumer's neck."
Based on the feedback that was obtained through ongoing monitoring, it was determined that this was the only Checkpoint from the 1999 release that was inadequate to prevent entrapment. Accordingly, this Checkpoint was updated and released on October 1, 2002 as:
"The side rails are located appropriately to prevent entrapment points at the headboard/footboard ends of the bed. ["Appropriately" means that with the bed flat, the side rails should be less than or equal to 2 1/3" inches or greater than or equal to 10" inches from the headboard/ footboard.
I would urge the FDA to include these dimensions in its final guidance.

Comment #6 relating to a dimensional limit for Zone 7, page 22 of the draft. This State's Checklist, Checkpoint #19 allows a 3" inch gap between the mattress and the headboard of a hospital bed. However, it has become a best practice to use a mattress that extends from the headboard to the footboard. The reason for this extra length is not to prevent an entrapment in Zone 7, but rather to use the headboard and footboard to stabilize the mattress on the bed deck. This additional surface contact with its resultant friction helps to prevent the mattress from sliding laterally, rotating and /or folding thereby creating and/or enlarging a gap in Zones #2 and #3.

Entrapment in Zone 7 has been a much larger issue with twin beds, not hospital beds. You will note that for twin beds Checkpoint # 16 sets forth an expectation that the headboard overlaps the top surface of the mattress by at least 2 ½" and Checkpoint #17 describes how the mattress in a twin bed should have only minimal space between the footboard and the mattress. Once again, I would urge the FDA to adopt the best practice of having mattresses extend from headboard to footboard and to include twin beds in its Guidance.

Comment #7 relating to articulated bed positions, page 23 of the draft. Most entrapment deaths in hospital beds take place when the head of the bed is elevated. The under bar entrapment potential of Zone 2 is significantly exacerbated when a full length bed rail is being used, see Figure 2. This Figure is taken from the User's Guide for the Bed Safety Checklist to illustrate Checkpoint #20, which states that:
"With the head of the bed raised, the triangular space between the bottom side rail and the mattress is not large enough to entrap a person."
As noted by the obvious entrapment hazard identified in Figure 2, I am strongly suggesting that the FDA include guidance for under bar gaps in articulated beds and particularly for those articulated beds with full length rails.

Comment #8 relating to the application of this guidance to all care settings, page 23 of the draft. I can only speak to the sector from which I am associated. Unless this Guidance significantly improves and aligns itself with the limits contained in the Bed Safety Checklist, I would urge that it not be used for the mentally retarded, developmentally disabled population. My rational for this request is as follows; the dimensional limits recommended in this guidance for the two most critical entrapment zones, i.e. Zone 2 and Zone 3, are over six times larger than our proven standards. Our residents have been asphyxiated in gaps that were much smaller than those permitted by this Guidance.

Also, in its present form, this Guidance is silent about issues that are of critical importance to this population. These issues include articulated beds, twin beds, mattress widths, headboards, and attachment hardware. All of these situations and items have contributed to entrapment deaths within the mentally retarded, developmentally disabled population.

Summary: Table 1, below, presents a comparison of the dimensional limits that are under review.

Table 1

Zones	Recommended Limits	Alternative Limits	Bed Safety Checklist Limits
Zone 1	< 4 ¾"	None	< 2 1/3"
Zone 2	< 4 ¾"	<2 1/3"	< 0"
Zone 3	< 4 ¾"	<2 1/3"	< ¾"
Zone 4	<2 1/3"	None	None
Zone 5	Not Specified	<2 1/3" or >12 ½"	<2 1/3" or > 10"
Zone 6	Not Specified	<2 1/3" or >12 ½"	<2 1/3" or > 10"
Zone 7	Not Specified	< 2 1/3"	Best Practice 0"

It has been my experience in working with the Bed Safety Checklist that the first issuance of dimensional standards is the one that sticks in peoples' minds and therefore has the greatest impact on all bed systems. The dimensions contained within the Bed Safety Checklist have been extensively applied during the past 5 years with a population at extreme risk of entrapment. The 60 million patient days without an entrapment death is beyond good luck. This fact verifies that these dimensions work and if adopted they would not need to be upgraded at some future time in order to yield safe bed systems for all users.

Bed Safety Checklist *(Updated 10/2002)*

Individual: _____ Address: _____

For both standard twin and hospital beds:

1. Yes __ No __ A risk assessment has been completed for the person, and a determination made that bed rails are required for safety.

2. Yes __ No __ With the mattress pushed against one side rail, the space between the mattress and the other side rail is minimal, if any. ["Minimal space" is when you feel resistance on both sides of your **OPEN** hand when you place it between the mattress and the side rail.]

3. Yes __ No __ The mattress is in good, firm condition, and can support a person's weight without excessive compression on the sides. [This should be determined with individual or person of equivalent size in the bed.]

4. Yes __ No __ Bed sheets are a proper fit. ["Proper fit" means that the mattress is not compressed when the sheets are used on the mattress.]

5. Yes __ No __ NA __ If needed, cross bars and side rails are appropriate for use with the person's bed. ["Appropriate for use" means the cross bars and side rails are compatible with the bed as defined by manufacturer's instructions.]

6. Yes __ No __ The bed rails, including cross bars, locking mechanism and side rails, are not damaged or broken.

7. Yes __ No __ NA __ All four pull pins or other securing mechanism actually lock and hold the side rails in the up position.

8. Yes __ No __ NA __ The side rails are located appropriately to prevent entrapment points at the headboard/footboard ends of the bed. ["Appropriately" means that with the bed flat, the side rails should be less than or equal to 2 1/3 inches, or greater than or equal to 10 inches from the headboard/footboard.

9. Yes __ No __ NA __ Both cross bars are adjusted for a tight fit and all push buttons are locked into the adjustment holes.

10. Yes __ No __ NA __ The bottom bar of the side rail overlaps the side of the mattress.

11. Yes __ No __ There are no gaps covered or filled by any devices, such as pads, pillows or bolsters.

12. Yes __ No __ NA __ If bed-rail covers/side-rail pads are used to protect a person from impact injuries, there are NO tears, rips, loose straps, etc. They are also securely attached to the side rail.

13. Yes __ No __ Spacing between the bars (inter-bar) is appropriate to the size of the person to prevent injury or entrapment. ["Appropriate spacing" for a child or small adult will be less than for an adult of "normal size." If a person is 35 inches or less in height, the space between the side rails must be 2 1/3 inches or less.]

14. Yes __ No __ The side rails are high enough to prevent the person from rolling out of bed, particularly when the specialty mattress and/or alternate positioning wedges are used.

For standard twin beds:

15. Yes __ No __ The bed frame, mattress and box spring are the same width.

16. Yes __ No __ NA __ When a headboard is used, it overlaps the mattress by at least 2 ½ inches.

17. Yes __ No __ NA __ When a footboard is used, the space between the mattress and footboard is minimal. ["Minimal space" is when you feel resistance on both sides of your open hand when you place it between the mattress and foot board with the mattress pushed against the headboard.]

For hospital beds:

18. Yes __ No __ The mattress is at least the same length and width as the bed deck.

19. Yes __ No __ With the bed flat and the mattress pushed against the headboard, there is a maximum of a 3" gap between the mattress and the footboard. [This space is to allow for adjustment of mattress position.]

20. Yes __ No __ With the head of the bed raised, the triangular space between the bottom side rail and the mattress is not large enough to entrap a person.

21. Yes __ No __ NA __ If split side rails are used, with the bed flat, the rails are either less than 2 1/3 inches apart or more than 10 inches apart.

(Note: There is a wide variation in the operation of hospital beds. The following checkpoints may not be appropriate for the specific type of hospital bed being reviewed. In these instances, refer to manufacturer instructions.)

22. Yes __ No __ NA __ Each cross bar is attached to either both sides of the frame or to both sides of the bed deck.

23. Yes __ No __ NA __ Both side rails telescope smoothly when the head or foot of the bed is raised and lowered.

24. Provide detailed comments for any NO response above:

Reviewer: _____ Date: _____

An Overhead View of Bed Rails on a Twin Bed

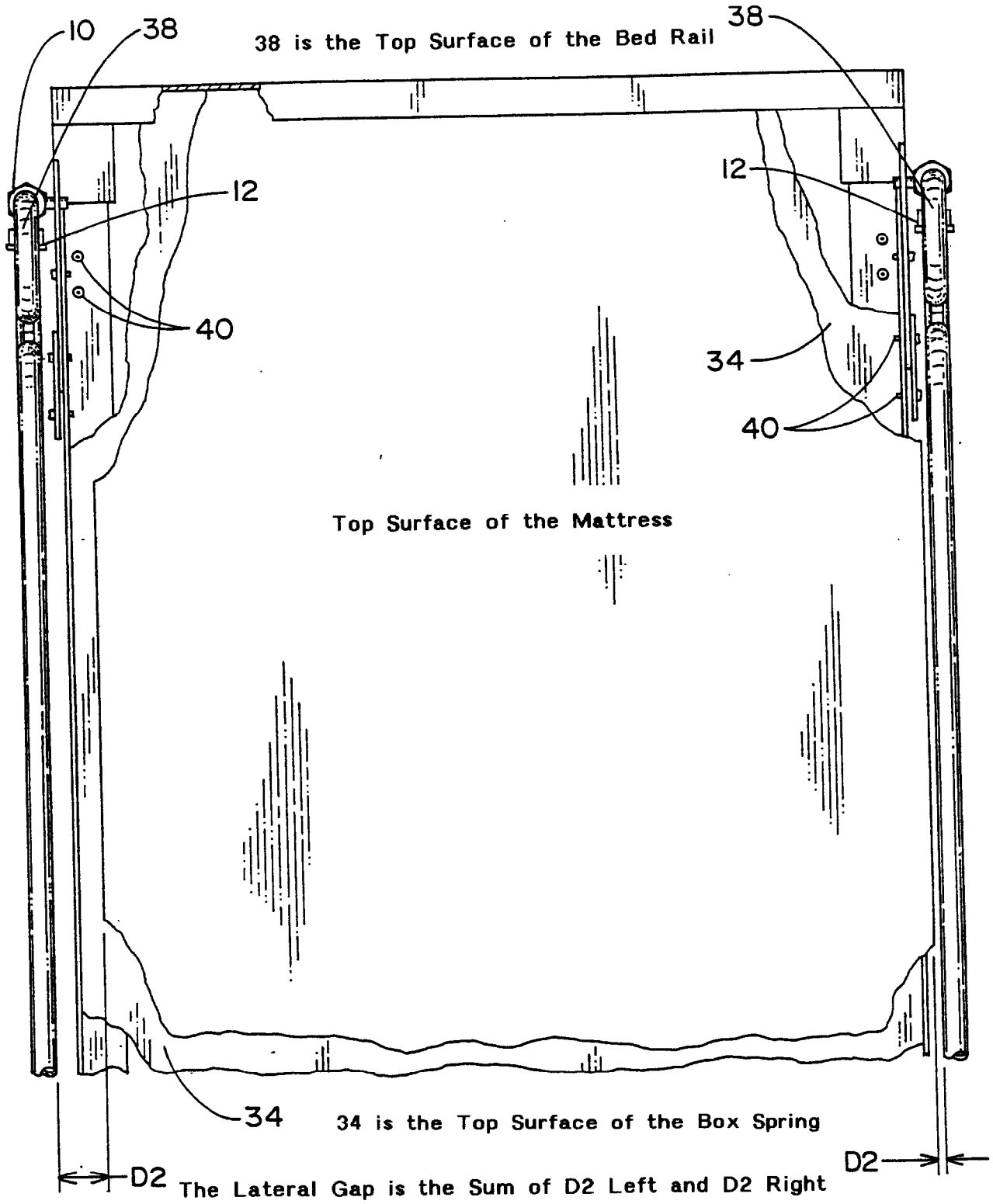

FIGURE 1

The triangular gap created when the head of the hospital bed is raised

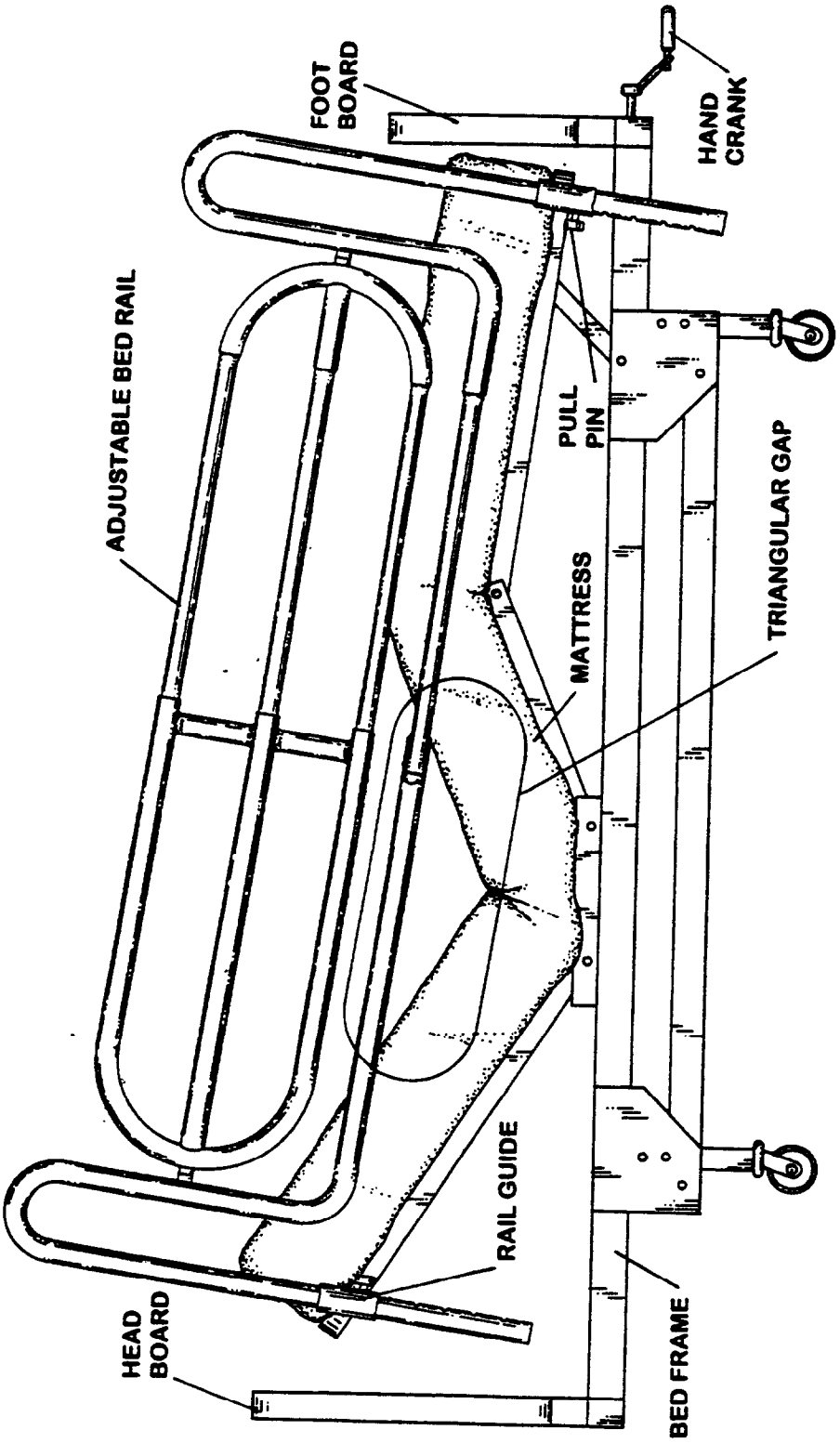

FIGURE 2